

The Maryland Board of Pharmacy Public Minutes - August 19, 1998

President David Russo called the meeting to order at 8:47 A.M. The Board recessed for lunch at 12:45 P.M. and returned to the Public meeting at 2:25 P.M. after a scheduled 1:30 P.M. reinstatement hearing during the executive session. In attendance were Commissioners Stanton Ades, Wayne Dyke, Barbara Faltz Jackson, Melvin Rubin, Laura Schneider, Donald Yee, Jeanne Gilligan Furman, Raymond Love and W. Irving Lottier, Secretary; Board Counsel Paul Ballard; Board Staff, David Denoyer, Tamarra Banks, Cheryl Cresic and Norene Pease, Executive Director. Commissioners Ramona McCarthy Hawkins and Rev. William Johnson were excused and were absent from the meeting.

Guests present include:

Randy Prine, DuPont
Paula Farmer, DuPont
Dorothy Levi
Gerry Roberts, PEAC
Nathan Gruz
Tracy Baroni, NACDS
Marvin Freedenberg, NeighborCare
Bob Chang, Drug Control
Samuel Thomas, Knoll Pharmaceutical
David Sellis, NeighborCare
Rick Pollhammer, NeighborCare
Kathleen Laegen, Barr Laboratories
Richard Davis, DuPont
David B. Moore, MSHP
William Popomaronis, EPIC
Pete Green, McKesson
Mailaka Flamer, Pharmacy Student

Recusals - President Russo requested that any member of the Board with a conflict of interest relating to an item on the agenda should notify the Board at this time. Stanton Ades asked if he should recuse himself from the NeighborCare Presentation which President Russo and Paul Ballard, Board Counsel discussed and it was decided this was an informational presentation and therefore no need for Mr. Ades to be recused.

Minutes - A motion was made by Barbara Jackson and seconded by Donald Yee to approve the July Board minutes. The minutes were approved.

Executive Director's Report

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Norene Pease reported that the Legislative Officer Position was offered to and accepted by Pamela Wiggin, who is both a registered nurse and an attorney. Ms. Wiggin will begin employment with the Board of Pharmacy on September 9, 1998.

Rush Building Spring Grove Hospital Center - Ms. Pease updated the Board regarding the potential move to Spring Grove Hospital property stating that BPQA has written to the Department indicating there is insufficient space for BPQA, Dental, Occupational Therapy and the Pharmacy Boards to occupy the Rush Building. A meeting will be scheduled at a later date to see if a suitable solution can be arranged.

NABP-AACP Meeting Status - David Denoyer gave a brief review. The District II Meeting will be held on October 22nd, 23rd and 24th, at the Baltimore Hilton. Pharmacy student Mailaka Flamer reported that donations so far have been \$6,100 in funding with \$4,000 additional from chain drug stores.

Mailing of Law Books - It was reported that the Law Books have been mailed to every pharmacy licensed by the State. The Board provided the postage and envelopes and MPhA provided the binders, inserted all materials and mailed them.

Hiring a part-time Office Assistant - Ms. Pease stated that the Board is in the process of recruiting as office assistant, an entry level position in State Government to take the place of the senior aide who resigned. The office assistant will verify the before and after images of licenses entered into the mainframe as required by the legislative auditors. The position will also assist in processing license renewals, filing and copying. Members of the Board endorsed the hiring of an office assistant.

Ms. Pease asked for ideas regarding the Technology Convention to be held in December 1998. It was suggested a display on how technology/robotics is now used in pharmacies compared with items from the pharmacy of the past. Ms. Pease asked for a member of the Board to help with ideas. Jeanne Furman volunteered to help with the planning and execution of the conference. Barbara Jackson also expressed an interest in encouraging school children to participate in the program,

Board Counsel's Report

No formal report was requested from Mr. Ballard.

Guest Presenter

CareMax Program - David Russo gave an overview regarding patient confidentiality within the

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McKesson/CareMax Program. Mr. Russo explained that the Board was concerned that the program was being implemented in the past in a format which was not in compliance with Maryland Law, and that patient confidentiality of prescription records used for patient compliance programs was a concern of the Board. Pete Green, V.P. Sales for McKesson Drug Co. explained how the "Patient Care" program works and discussed with the Board the Universal Signature Log and the patients right to opt In or opt out of patient care programs. He further stated that no pharmacies in Maryland are participating in patient care programs at the present time. Suggestions were made to Mr. Green on how to better educate the patients about the program so an informed decision to participate or not to participate can be made. It was also suggested that the pharmacist be more involved and explain the program to disabled customers.

The Board voiced concerns regarding the opt out program and questioned if this means pharmacies must get out of the Omni-link system completely.

Board members also expressed concerns about patients receiving letters from pharmacies with the pharmacist name on the letters, when the pharmacist was not informed and had no knowledge of the letter. Mr. Green stated that the pharmacist would, in the future receive notice of outgoing letters. Mr. Russo had concerns regarding the automatic (programed into the data system) initial transmission of information. He questioned how the transmission could or would be reversed once the confidential patient information had already been transmitted to another location or user for follow-up? Mr. Green stated that pharmacists could reverse the data base indicating that refill reminder letters or any other information should not be sent to persons opting out of the program. The Board wondered how such confidential information could be reversed after it had already been released and suggested that patients should be given the opportunity to opt out of the program before it is initiated, rather than a passive patient approach that assumes a person has opted in if they have not clearly indicated the intent to opt out. Dr. Love suggested that an explanation of what patients are signing be clarified to them in an easily understandable format. Mr. Green stated that he felt this was a workable solution. Board members stated that total patient awareness as to how the program works should be explained to patients before a prescription is filled.

Bill Popomaronis, Epic pharmacies, stated that he keeps his pharmacists informed about the programs, and how to educate and inform patients about them. Mr. Popomaronis feels this is a positive program and is willing to work towards addressing all problems concerning confidentiality in order to have it implemented effectively while preserving patient confidentiality

Concerns were expressed regarding the use of an outside entity for mailers. Who protects the confidentiality of the information when it is in the hands of the entity that performs the mailing? Mr. Green said he will provide the Board with information on how confidentiality is maintained by mailing entities. Does McKesson have a policy regarding how to handle confidential patient data.

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Mr. Green stated no, but said it is a good point and a policy could be developed.

Mr Russo asked what the time line was to implement the program and Mr. Green responded by saying they are ready as soon as an agreement is reached with the Board of Pharmacy. The Practice Committee will discuss the issue at the September 8, 1998 meeting and will have a report at the September 16, 1998 Board Meeting. Mr. Green will send all information requested by the Board to Ms. Azrael, Delegate to the Women's Law Center of Maryland and to David Denoyer.

Committee Reports

Licensing Committee - Wayne Dyke reported that the Fall Examination will be on Tuesday, October 13, 1998.

Reciprocity - Mr. Dyke reported that there were 22 reciprocity candidates and a motion was made by Barbara Jackson and seconded by Laura Schneider, that all candidates be approved for licensure with the exception of Commie Anana, Paul S. Rydel and Farrokh a. Yazdy, who will be licensed when the Board receives their Oral English competency certificates. The motion was approved. The candidate names are: Commie Anana, Steven A. Blackwell, Jacqueline a. Crank, Dat T. Doan, Jeffrey S. Duerr, Bena Easo, Dena B. Foley, Michelle L. Grale, Meeta Kamani, Leonard G. Kessler, Hing H. Khov, William Loub, Teresa A. Mars, Eileen E. Nolte, John P. Rose, Julie A. Roskopf, Paul S. Rydel, Diane C. Smith, Tuyet-Nhung Minh Tran, Jonette L. Vagts, Gretchen S. Welge and Farrokh A. Yazdy.

Legislative Committee

Norene Pease reported that the next Strategic Planning Meeting will be on September 10, 1998.

Regulation Update

Code of Conduct - The Board discussed the Code of Conduct and Paul Ballard, Board Counsel was asked to review Health General on Patient Privacy and Confidentiality and submit his comments to the Practice Committee for review at the September 8, 1998 meeting.

Ray Love moved to amend the Code of Conduct to omit section .03 B and leave in .03 A which was seconded by Stanton Ades. Barbara Jackson abstained from this vote. The Board approved.

Ray Love had concerns regarding the term pharmaceutical equivalent and suggested that these terms in .01 C paragraph 1 and paragraph 2 be omitted.

.01 C2 the last line should read in both paragraphs (has authorized interchanges). Ray Love

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proposed this amendment which was seconded by Barbara Jackson and approved by the Board.

.08 Refusing to Dispense for religious reasons, after discussion President Russo recommended that the Board wait until the legislature discusses this issue and formulates law on how to address this issue. Members of the legislature have introduced bills to clarify how health professionals may refuse to provide medical services based on religious concerns. Laura Schneider moved to change the title in .08 to read Refusing to Dispense Controlled Substances in order to clarify the material addressed in the section. The motion was seconded by Barbara Jackson and approved by the Board.

NORD Form-10.34.09 Fees (Amendments to .02 & .03) - Norene Pease gave a brief overview regarding reserve funds. The Board has a larger reserve fund than is necessary. Ms. Pease proposed providing a benefit to the licensees who contributed to the reserve by waiving the fee's for manufacturers and distributors during 1998 and reducing the renewal fee for manufacturers and distributors to \$250.00 effective November 1999. Immediate action is needed to develop an emergency regulation to allow the Board to waive the fee in November 1998.

Melvin Rubin motioned to waive the manufacturers and distributors fee in 1998 and to reduce the in fees to \$250.00 in 1999. The motion was seconded by Barbara Jackson and approved by the full Board.

The Board received final confirmation that the fee for the State pharmacy examination has been reduced to \$50.00.

Response to S.B. 144 Code of Conduct for Board Members and Investigators & Proposed Regulations - 10.31.01 Code of Conduct for Board Members and Investigators - Section .03 B. (1) (b) Recusal of Board Members.

Dr. Love commented that in instances where the matter involves a business organization or a group practice it may be necessary for the Board member to discuss the matter with other individuals. For instance, the licensee may need to be disciplined or instructed. This interaction may be outside of the matter before the Board. Dr. Love suggested that either the term matter needs to be defined or the committee developing the regulation could find another way to remedy this dilemma.

Final action 10.19.03 Controlled Substance - Mr. Denoyer introduced the report from DHMH stating that the period for pharmacists to receive from the prescriber a written prescription after emergency dispensing is now officially 7 days.

Assisted Living Proposal from Licensing and Certification Division - Nathan Gruz of MPhA expressed his concerns regarding the Assisted Living Regulation which designates responsibilities

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for drug review to Nurses in some cases. He suggested on site review by a pharmacist for medication errors instead of nurses having this responsibility, which he feels would create numerous potential problems. Mr. Gruz stated that pharmacists are best qualified to assure the safety of medications in Assisted Living facilities and feels the regulation should designate pharmacists as the responsible party. Mr. Gruz asked the Board of Pharmacy to support this action. Discussions were held regarding how to proceed. Comments on this regulation should be forwarded by August 31, 1998 to Michele Phinney from David Denoyer. President Russo assured Mr. Gruz that the Board would do its part to voice concerns, about the development of the regulations and to include interested parties by keeping them informed.

PEAC Update

PEAC Representative's Report - Stanton Ades introduced Gerry Roberts. Ms. Roberts spoke about PEAC's Annual Retreat. She stated that PEAC is now a not for profit organization and can conduct fund raising activities. She informed the Board that PEAC has obtained the legal opinion that the organizations case records are not considered medical records, therefore PEAC does not have to retain them for a specified amount of time or maintain their confidentiality. New members are needed as case monitors. PEAC is attempting to recruit 20 new members.

With regard to the pharmacist renewal form, PEAC suggests that the Board add new language to the questionnaire on the back of the form, i.e. a Yes response with an explanation to the questions inquiring about conviction status that will not necessarily jeopardize license status.

PEAC also is moving to work with chain drug stores to support a chain store initiative to cooperate with PEAC to recognize drug and alcohol addiction problems, as opposed to firing pharmacists found to have such problems. Ms. Roberts noted that the next PEAC meeting will be Thursday, August 27, 1998.

Pharmacy Rehabilitation Committee RFP Development - Norene Pease stated there was nothing to report at this time and promised a report at a later date.

Pharmacy Practice Committee - Stanton Ades gave a review of the meeting on August 10, 1998.

Formulary Advisory Committee - It was reported that the Board recommended to Secretary Wasserman that the Department should study the issue of generic substitution of the drugs on the list of disqualified drugs which are now "A" rated by the FDA. The Board discussed creating an advisory committee to be appointed by Secretary Wasserman. Discussion also included how to inform Delegates Elliot and Bozman about the Advisory Committee. The Committee would make recommendations to Dr. Wasserman, he will decide whether or not to implement the recommendations of the Committee by proposing to make changes to COMAR.

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Support Personnel Task Force - Mel Rubin volunteered to chair a task force which would research the status of support personnel regulations in surrounding states. The task force will invite MPhA, Maryland Chapter of NACDS, MSHP, ASCP and a consumer representative.

Suburban Hospital - It was suggested that representatives from the Pharmacy Practice Committee visit Suburban Hospital to review the automated dispensing system and to make recommendations about the safety and security of the system. Commissioners Furman and McCarthy-Hawkins have expressed an interest in reviewing this system.

COMAR 10.34.20 Proposal - Electronic Transmission of Prescriptions - This proposal is being circulated to prescriber boards and to the Department. Tracy Baroni from NACDS voiced concerns with regulation .03, requirements. David Russo asked Ms. Baroni for suggestions and she will send information to the Board. Mr. Russo also suggested that someone talk to BPQA and explain the confidentiality issue from the point of view of the Board and from prescribers. Mr. Russo called for any motions, and in the absence of a motion, the regulation will proceed.

Discussion at the next Practice Committee meeting will include pharmacy security and the code of conduct issues.

The following additional issues have been referred to the Pharmacy Practice Committee for discussion: developing regulations for patient confidentiality, and developing regulations for the use of robotics in various pharmacy settings.

SB 782 established an advisory committee on Home-Based Health Care Services within the Department. Mr. Ades is the Board's representative to the Committee which has been formed to oversee the quality of home-based health care and recommend whether oversight should be strengthened, streamlined reduced or eliminated and to examine employment issues relating to liability for paying benefits such as Social Security, workers' compensation and unemployment insurance. Recommendations for changes will be forwarded to the Secretary of DHMH by the end of December 1998.

Budget Committee

Media Campaign MMA - Tamarra Banks reported that on Tuesday, August 4, 1998 an agreement was reached to resolve the issue of outstanding payments to MMA. Ms. Banks assembled a new sole source contract to pay the outstanding amount, met with MMA and delivered the contract to Russ Jenkins of the Department's Contracts Division. Russ Jenkins approved the new contract for the outstanding amount of \$21,000.

F.Y. 2000 Budget Development - Tamarra Banks reported that a draft FY2000 budget of

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\$841,000 has been completed. The Board's bottom line total is higher than the Department's request for 5% growth for Boards & Commissions. The items affecting the Board's increase are per diems and that the Pharmacist Compliance Officer's (PCO) position, which appears twice in the budget.

Regular permanent positions are difficult to obtain, Ms. Banks explained that the PCO's position will remain in the budget as a regular permanent position until the Board's request to move it contractually to the University of Maryland has been approved.

Mr. Lottier addressed the issue of the per diem increase by requesting that Board Members use more discretion, projected amounts should parallel Boards of similar size, and that new policies will be created to control per diem reimbursements. The new policy would restrict reimbursement for committee meetings to chairpersons and committee members, eliminate claims for certain functions; such as the new members dinner and closely monitor Board Member's office visits. Mr Lottier acknowledged that the introduction of new legislation in FY97 and FY98 were responsible for per diem increases in previous years.

Ms. Banks asked if the committee meetings listed in the FY2000 draft budget accurately reflect the meetings Board Members will attend. Barbara Jackson stated that the Consumer Advisory Group, which consists of all consumer members from all Boards needs to be included in the budget.

Barbara Jackson moved to approve the Budget seconded by Stanton Ades. The budget was approved by the Board.

Questions for the Board

New Inquiries

Pfizer, Inc. - requested the Board's for policy or dispensing laws regarding whether or not out-of-State or foreign prescriptions are valid in Maryland - Paul Ballard will research out of State prescribers as authorized prescribers under the Maryland Pharmacy Act. He suggested that improvements in the law may be needed for clarification.

Dr. Frank Kasik - drug delivery question - The Board discussed this issue and it was stated that delivering a single drug for one person at the front desk of a building would be acceptable. It was further stated that a collection of drugs to be delivered to various persons throughout the building would not be safe or appropriate. David Denoyer will research if other states have any regulations concerning a drop off point (depot) and draft a response for Dr. Kasik.

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Licensure requirements for the Regional Cancer Center - The Board discussed the issues regarding the Satellite Pharmacy and it was agreed that since this is a separate pharmacy location it would need a separate pharmacy license. Barbara Jackson motioned and Donald Yee seconded the motion to require an additional license and the Board approved the motion.

Informational

The Board discussed the physician letters regarding generic Coumadin (warfarin). The issue of generic substitution and the legality of the letter sent from the doctor covering all prescriptions written from a particular doctor versus attaching a letter to a prescription directly pertaining to that prescription was discussed. Board members agreed that the law requires a prescription to have some sort of indication that substitution is restricted, and this sort of blanket restriction would not have the desired legal effect. Pharmacists should communicate with prescribers to determine true intent for each individual patient. Mr. Lottier will notify the pharmacy community via newsletter, regarding the generic prescription letters. Melvin Rubin offered to have this put in the MPhA newsletter.

Letter to Pharmacists from DuPont re: Coumadin - The Board discussed the letter with no action taken.

Lifescan Blood Glucose Meters Recalled - Board discussion with no action taken.

FDA meeting - CDER Stakeholders - David Denoyer gave brief overview and he asked that he be informed of any issues concerning the Board.

News release-First Disease State Management Exams Administered - Board discussed with no action taken.

Long term care compliance - Letter from Jack Freedman - Board discussed with no action taken.

Open letter regarding Regulating Pharmaceutical Care Outcomes Questionnaire II - Board discussed with no action taken.

Follow - Up Letters

No discussions were held concerning follow-up letters

NeighborCare Presentation

David Sellis and Rick Pollhammer introduced themselves and gave a overview of the

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NeighborCare automation program. They described a standardized method of dispensing and how patient care and accuracy would be improved as a result of bar coding and scanning. Patient doses would be loaded into a drawer by a robot, similar to currently used hospital systems. Mr. Pollhammer stated that this system would provide better labeling and allow nursing time to be used more efficiently. The Board expressed concerns regarding back up procedures and were told that generators for power failures and backup profiles would be done day to day for computer failure. Mr. Russo also questioned how pharmacist responsibility for a particular cart fill would be assigned if the cart was not personally checked. Mr. Pollhammer stated that these issues could be worked out, as long as the Board did not have problems with the concept. Mr. Pollhammer stated that the new system should be safer for the patient than current manual methods of checking cart fills.

Mr. Russo suggested a committee be formed to make a site visit to the NeighborCare offices to observe the system in operation. Jeanne Furman and Ray Love expressed an interest in participating in such a committee. It was also suggested that Ramona McCarthy Hawkins observe the system. Ray Love stated that he would like the Pharmacy Practice Committee to develop regulations on the use of robotics in various settings. Mel Rubin suggested a work group to study the use of robotics and to report recommendations to the full Board.

Mr. Russo adjourned the public meeting.

Respectfully Submitted,

W. Irving Lottier
Secretary